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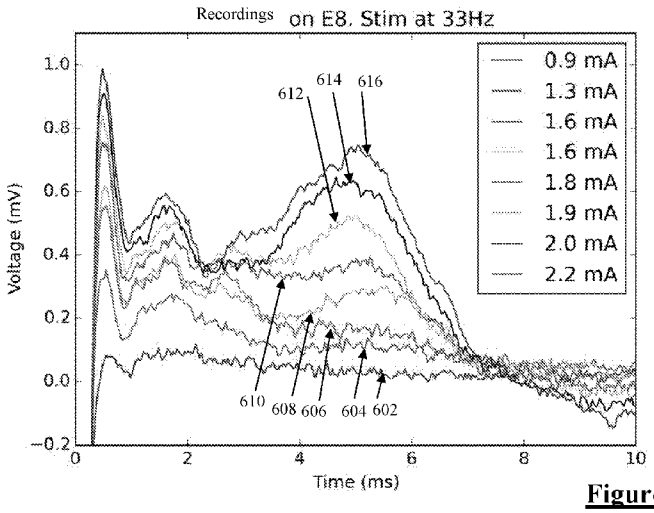

Figure 6

(57) Abstract: A method of determining a cochlear implant recipient's comfort level. Electrical stimuli are delivered to the cochlea. At least one electrode of the implanted cochlear implant is used to obtain recordings of neural responses evoked on the cochlear nerve by the electrical stimuli. The recordings are inspected to detect a diagnostic signal component, such as onset of a stapedius reflex. The comfort level is determined from the diagnostic signal component. Also a method for dynamically adjusting neural stimuli to compensate for neural accommodation. A stimulus is adjusted by reference to a stimulation history and a map of neural accommodation then delivered to neural tissue.

WO 2017/100866 A1

MEASUREMENT OF NEURAL RESPONSE

Cross-Reference to Related Applications

[0001] This application claims the benefit of Australian Provisional Patent Application No. 2015905289 filed 18 December 2015, which is incorporated herein by reference.

Technical Field

[0002] The present invention relates to the measurement of the auditory response and for example to a method of electrically monitoring a stapedius reflex or the like, using implanted cochlear implant electrodes, to determine a patient's comfort threshold. The present disclosure additionally or alternatively provides for dynamic mapping of neural excitation to provide for stimulus generation to occur in a dynamic manner to produce a desired neural response while allowing for neural accommodation to a stimulation history.

Background of the Invention

[0003] Cochlear implants apply electrical stimuli of variable intensity to evoke the sensation of sound. This is determined by using a mapping from acoustic sound intensity (loudness) to electrical stimulus intensity. These maps are typically parameterised by measuring threshold (T) and comfort (C) levels on each electrode, for each patient. When fitting cochlear implants it is therefore typical to obtain the implant recipient's input regarding their perceptions which arise in response to applied stimuli. However in some cases, such as when fitting pre-lingual infants or when fitting adults unable to provide reliable behavioural measures, limited or no subjective input can be obtained from the implant recipient. Without the implant recipient's input it is difficult to objectively measure or assess the implant recipient's T and C levels, as both are somewhat subjective in nature: the threshold (T) level is the least amount of electrical current necessary for a person to perceive a sound, and the comfort (C) level is the amount of electrical current which results in a loud but comfortable perception. The C level, or analogue thereof, in some applications is instead referred to as a Most Comfortable Loudness level (abbreviated as MCL or M level). Threshold can be measured using auditory brainstem response but it is expensive and time consuming. And, comfort level is more difficult to measure. Moreover, comfort level can vary widely between individuals, depending for example on the cause of deafness, and is thus important to measure for each individual.

[0004] In relation to objectively determining the T level, one approach is to measure the neural response to stimuli in order to determine a threshold level of stimulation at which evoked neural responses first arise on the auditory nerve. This level of stimulation does not always precisely match the recipient's perceptions, but can at least serve as an approximation of the correct T level. However, no such threshold can be observed from neural response measurements in order to objectively assess the C level, as there is typically no observable effect in neural responses which indicates that a loud but comfortable perception level has been reached.

[0005] In order to objectively generate an estimate for the C level, the stapedius reflex has been considered. The stapedius reflex involves contraction of the stapedius muscle in the middle ear in response to loud sounds, and thus may serve as a proxy for the threshold at which perceived sound becomes uncomfortably loud. The stapedius reflex can be seen intra-operatively, but the cochlear implant electrode current required for the stapedius reflex to become visible exceeds the patient's C level; i.e. by the time the stapedius reflex can be seen the stimulus level is too high and the perceived sound too loud.

[0006] Electrically elicited stapedius reflexes (EESRs) resulting from cochlear implant electrode stimulation can alternatively be measured by tympanometer and/or by needle electrodes inserted ipsilaterally. EESRs recorded by needle electrodes in human patients show latencies on the order of around 5-10ms, which increase in amplitude and decrease in latency as the current continues to increase above the stapedius reflex threshold. These methods of assessing the stapedius reflex threshold however require separate surgical or clinical tools which are moderately to significantly invasive and return only a single measurement.

[0007] Another issue in neurostimulation, and not limited to cochlear stimulation, is that nerves subject to electrical stimulation can undergo accommodation effects. These effects result in a transient change in the stimulation threshold of the nerve fibre. This may be an increase or a decrease in the neural response to a given stimulus, depending on the stimulation history which precedes the stimulus. Accommodation effects can have timescales from milliseconds to minutes. Multiple accommodation effects may be present in the same nerve fibre, for example a fast inhibition and a longer-term excitation may co-exist, complicating characterisation of accommodation.

[0008] Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

[0009] Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

[0010] In this specification, a statement that an element may be “at least one of” a list of options is to be understood that the element may be any one of the listed options, or may be any combination of two or more of the listed options.

Summary of the Invention

[0011] According to a first aspect the present invention provides a method of determining a cochlear implant recipient’s comfort level, the method comprising:

delivering electrical stimuli from at least one electrode of an implanted cochlear implant to the cochlear nerve;

using at least one electrode of the implanted cochlear implant to obtain recordings of neural responses evoked on the cochlear nerve by the electrical stimuli; and

inspecting the recordings to detect a diagnostic signal component and determining the comfort level from an observed onset of the diagnostic signal component.

[0012] According to a second aspect the present invention provides a device configured to determine a cochlear implant recipient’s comfort level, the device comprising:

a stimulation controller configured to control the delivery of electrical stimuli from at least one electrode of an implanted cochlear implant to the cochlear nerve;

a recording controller configured to control the recording by at least one electrode of the implanted cochlear implant of recordings of neural responses evoked on the cochlear nerve by the electrical stimuli; and

a processor configured to inspect the recordings to detect a diagnostic signal component and to determine the comfort level from an observed onset of the diagnostic signal component.

[0013] According to a third aspect the present invention provides a computing device configured to carry out the method of the first aspect.

[0014] In some embodiments of the first to third aspects of the invention, inspecting the recordings to detect a diagnostic signal component may comprise inspecting a time period of substantially 1-20 ms after the stimulus, and/or a time period 1-7 ms after the stimulus. Inspecting the recordings to detect a diagnostic signal component may in some embodiments comprise inspecting a time period of substantially 4-7 ms after the stimulus and/or a time period of substantially 1-3 ms after the stimulus and/or a time period of substantially 10-15 ms after the stimulus.

[0015] In some embodiments of the first to third aspects of the invention a recording obtained from a basal electrode is compared to a recording obtained from a more apical electrode in order to discriminate a diagnostic signal component. For example, a recording obtained from an extra-cochlear electrode may in some embodiments be compared to a recording obtained from an intra-cochlear electrode in order to discriminate a diagnostic signal component. The comparison may for example be of either or both of a time period of substantially 2-4 ms after the stimulus in each such recording, and a time period of substantially 4-7 ms after the stimulus in each such recording. A relatively stronger signal component in the basal electrode recording in the time period of substantially 2-4 ms after the stimulus coinciding with a relatively stronger signal component in the apical electrode recording in the time period of substantially 4-7 ms after the stimulus may be taken to be a diagnostic signal component.

[0016] In some embodiments of the first to third aspects of the invention a latency of a signal component is determined in order to discriminate a diagnostic signal component. In such embodiments, a reduction in latency with an increase in stimulus current may be taken to be a diagnostic signal component.

[0017] In some embodiments of the first to third aspects of the invention the diagnostic signal component sought may arise from activation of a neural or muscular system which presents a useful proxy for comfort level. For example the diagnostic signal component may arise from the stapedius reflex.

[0018] In some embodiments of the first to third aspects of the invention the stimulating and recording are performed repeatedly to improve the determination of the comfort level. For

example the stimulating and recording may in some embodiments be performed in the range 1 – 300 Hz, such as at a rate below 10 Hz, at a rate of 2 Hz, at a rate of 33 Hz or at a rate above 100 Hz.

[0019] It is to be appreciated that determination of a comfort level may comprise determination of the C level, M level or any analogue measure, and each such parameter definition of loudness perception level is within the scope of the present invention.

[0020] The diagnostic signal component may comprise any one, some or all of the signal characteristics discussed herein, combined in any suitable manner.

[0021] Determining the comfort level from an observed onset of the diagnostic signal component may comprise defining the comfort level as being the same as the stimulus current at which onset of the diagnostic signal component occurs. Alternatively, the comfort level may be defined as a different current level, calculated in any suitable manner from the stimulus current at which onset of the diagnostic signal component occurs.

[0022] The comfort level may be determined in accordance with the present invention in respect of each of a plurality of channels, a plurality of electrodes, and/or a plurality of frequency bands in order to yield a spectral mapping of comfort level.

[0023] According to a fourth aspect the present invention provides a method of dynamically adjusting neural stimuli to compensate for neural accommodation, the method comprising:

adjusting a stimulus by reference to a stimulation history and a map of neural accommodation in order to define an adjusted stimulus; and

delivering the adjusted stimulus to neural tissue.

[0024] According to a fifth aspect the present invention provides a device for dynamically adjusting neural stimuli to compensate for neural accommodation, the device comprising:

a recording medium holding data defining a map of neural accommodation;

a signal processor for taking an input signal and determining a stimulus therefrom, and for adjusting the stimulus by reference to a stimulation history and the map of neural accommodation in order to define an adjusted stimulus; and

a stimulus generator for generating the adjusted stimulus for delivery to neural tissue.

[0025] Embodiments of the fourth and fifth aspects of the present invention may thus provide a system for compensating for accommodation using a dynamic map. The technique for doing so may in some embodiments comprise a static map and an accommodation model.

[0026] The accommodation model may in some embodiments be fitted and/or adjusted using measurements of ECAPs. For example, ECAPs may be measured after every stimulus during normal use of the neurostimulator, or after selected stimuli during normal use.

[0027] The accommodation model may in some embodiments be fitted and/or adjusted using measurements of ECAPs at a time of fitting or installation of the neurostimulator, by use of probe stimuli to evoke the ECAPs. The probe stimuli may comprise a constant amplitude train, or may be adjusted to produce constant amplitude ECAPs. The probe stimuli may comprise a pseudorandom sequence. The probe stimuli sequence may be delivered on multiple electrodes for MIMO accommodation mapping.

[0028] The accommodation model may in some embodiments adjust a static stimulation map. The adjustment may comprise scaling T while leaving C unchanged. Alternatively the adjustment may comprise scaling total stimulus intensity so that both T and C are adjusted. Other embodiments may select different map curves depending on state or stimulation history.

[0029] The accommodation model may in some embodiments apply to a single electrode, and may take into account only the stimulation history of that electrode. Alternatively, the accommodation model may in some embodiments reflect a stimulation history of more than one electrode.

[0030] The accommodation model may in some embodiments comprise a linear filter. An input of the linear filter may be clamped, or a state variable of the filter may be clamped.

[0031] An input to the accommodation model may in some embodiments comprise stimulus current, or in other embodiments stimulus charge such as in the case of variable pulse widths.

[0032] Embodiments of the fourth and fifth aspects of the present invention may provide a system for compensating for accommodation in a cochlear implant, a deep brain stimulator, a spinal cord stimulator, a retinal or optic nerve stimulator, or the like.

[0033] Other embodiments of the fourth and fifth aspects of the present invention may provide a system for achieving consistent neural response in the presence of accommodation by using adaptive filtering. In such embodiments, the adaptive filter may be trained using the difference between desired and recorded characteristic, such as ECAP output. In some embodiments filter training is suppressed during periods without stimulation. In some embodiments the filter produces zero output when stimulation is not desired. In some embodiments the filter is affine for nonzero inputs. The adaptive filtering may be applied in a SISO manner in respect of a single electrode or a single channel, or in a MIMO manner in respect of a plurality of electrodes or channels.

[0034] In another aspect the present invention provides a method of training a system for compensating for neural accommodation, the method comprising measuring neural accommodation characteristics arising in response to a sequence of stimuli, and defining a map of neural accommodation. For example an ECAP characteristic may be measured for such training. The ECAP characteristic may comprise one or more of: amplitude of a component, a detector output, a latency of a component.

[0035] Further embodiments of the invention provide for mapping the therapy variable to a desired ECAP characteristic. The map of the therapy variable to the desired ECAP characteristic therapy may for example be combined with a percept-to-ECAP map for sensory stimulation, combined with a loudness-to-ECAP map for cochlear implants or auditory brainstem implants, or combined with a light-to-ECAP map for retinal prostheses

Brief Description of the Drawings

[0036] An example of the invention will now be described with reference to the accompanying drawings, in which:

Figure 1 illustrates a cochlear implant system in accordance with one embodiment of the present invention;

Figure 2 is a block diagram of an implanted neurostimulator;

Figure 3 is a schematic illustrating interaction of the implanted stimulator with a nerve;

Figures 4-8 show the signals demonstrating the stapedius reflex;

Figure 9 illustrates a prior cochlear implant architecture;

Figure 10 illustrates a prior cochlear implant mapping;

Figure 11 illustrates prior clinical mapping adjustment estimations to compensate for broad spectrum loudness summation;

Figure 12 illustrates prior clinical mapping adjustment estimations to compensate for pre-lingual subjects;

Figure 13 illustrates the nature of neural adaptation or accommodation;

Figure 14 is a schematic of data flow in a cochlear implant;

Figure 15 is a schematic of an embodiment of the invention using a dynamic map for neural adaptation compensation;

Figure 16 is a schematic of an embodiment of the invention using a dynamic map for neural adaptation compensation for each electrode;

Figure 17 is a schematic of an embodiment of the invention using a dynamic map for neural adaptation compensation for each electrode;

Figure 18 is a schematic of an embodiment of the invention using a MIMO dynamic map for neural adaptation compensation;

Figure 19 is a schematic of an embodiment of the invention using a MIMO dynamic map for neural adaptation compensation; and

Figure 20 is a schematic of an embodiment of the invention using an adaptive filter for neural adaptation compensation.

Description of the Preferred Embodiments

[0037] Figure 1 illustrates a cochlear implant system 10 in accordance with one embodiment of the present invention. The system 10 comprises an external sound processing device 12, an external transceiver coil 14, an implanted transceiver coil and pulse generator 16 in communications with the external coil 14, and an electrode lead 18 carrying multiple electrodes 20, of which three are shown in Figure 1 but any suitable number may be provided. Processor unit 12 controls the delivery of stimuli to the electrodes 20 in order to deliver electrical stimuli to the cochlea and evoke neural responses upon the cochlear nerve 22 for perception by the brain as a supplement to or substitute for the normal hearing mechanism for the hearing impaired. Electrodes 20 are also in close proximity to the middle ear, in particular the stapes 24 and stapedius muscle (not shown).

[0038] Figure 2 is a block diagram of a neurostimulator 100. Module 110 contains a battery 112 and a telemetry module 114. In embodiments of the present invention, any suitable type of transcutaneous communication, such as infrared (IR), electromagnetic, capacitive and inductive

transfer, may be used by telemetry module 114 to transfer power and/or data between an external device and the electronics module 110.

[0039] Module controller 116 has an associated memory 118 storing patient settings 120, control programs 122 and the like. Controller 116 controls a pulse generator 124 to generate stimuli in the form of current pulses in accordance with the patient settings 120 and control programs 122. Electrode selection module 126 switches the generated pulses to the appropriate electrode(s) of electrode array 150, for delivery of the current pulse to the tissue surrounding the selected electrode. Measurement circuitry 128 is configured to capture measurements of neural responses sensed at sense electrode(s) of the electrode array as selected by electrode selection module 126. In the case of the cochlear implant system 10 shown in Figure 1, the components of module 110 can be distributed in any suitable manner between the external sound processing device 12 and the implanted transceiver coil and pulse generator 16, and the present invention encompasses such variations in architecture.

[0040] Figure 3 is a schematic illustrating electrical interaction of the implanted stimulator 100 with a nerve 180, in this case the auditory nerve and other proximal tissue including the stapedius muscle. Electrode selection module 126 selects a stimulation electrode 2 of electrode array 150 to deliver an electrical current pulse to surrounding tissue including nerve 180, and also selects a return electrode 4 of the array 150 for stimulus current recovery to maintain a zero net charge transfer.

[0041] Delivery of an appropriate stimulus to the nerve 180 evokes a neural response comprising a compound action potential which will propagate along the nerve 180 as illustrated.

[0042] The device 100 is further configured to sense the existence and intensity of bioelectrical responses to the delivered stimuli including sensing both compound action potentials (CAPs) propagating along nerve 180, whether such CAPs are evoked by the stimulus from electrodes 2 and 4 or otherwise evoked, and also including sensing bioelectrical activity from other sources which give rise to measurable electrical fields at the measurement electrodes 6 and 8. To this end, any electrodes of the array 150 may be selected by the electrode selection module 126 to serve as measurement electrode 6 and measurement reference electrode 8. Signals sensed by the measurement electrodes 6 and 8 are passed to measurement circuitry 128, which for example may operate in accordance with the teachings of International Patent

Application Publication No. WO2012155183 by the present applicant, the content of which is incorporated herein by reference.

[0043] The present invention recognises that when measuring the evoked response with a low artefact amplifier, the stapedius reflex can be seen in the recordings obtained from the cochlear implant electrodes, and the stapedius reflex arises approximately 5ms after stimulation and temporally separate to evoked response on the auditory nerve. The stapedius reflex has an onset that, in the recordings obtained from the cochlear implant electrodes, appears gradually with increasing stimulus current. The gradual onset of the stapedius reflex cannot be seen visually by surgeons intra-operatively. Also, for a patient who has their implant surgery complete, the stapedius reflex cannot be seen at all.

[0044] Figures 4-8 show recordings obtained from cochlear implant electrodes in accordance with the present invention, and demonstrating the stapedius reflex. Specifically, Figures 4-8 illustrate the evolution of the observed stapedius reflex signal with changes in stimulus current.

[0045] It is to be noted that it is a useful diagnostic that the stapedius reflex appears gradually in response to increasing stimulus currents. At high sound volumes, the function of the stapedius muscle is to separate the ossicles slightly, which serves to reduce the signal to the cochlea but not to the point of total attenuation. The present invention recognises that the cochlear implant electrodes can be exploited to perform electromyography to sense this behaviour of the stapedius muscle electrically. This observable signal is referred to herein as the evoked stapedius electrical response (ESER). For completeness it is noted that the aforementioned EESR is a muscle response from electrical stimulation, while the ESER is an electrical measurement following EESR. This requires a suitable low-artefact amplifier as described above in relation to Figures 1-3. The present invention further recognises that the ESER forms a useful measure or indicator of a patient's C level.

[0046] Some embodiments of the present invention further provide for determining comfort level from an observed ESER onset level, by comparison to previous measurements of an average or typical ratio or relationship between ESER onset and C levels across a control group of lingual patients. The ratio or relationship may then be applied to deduce a non-lingual patient's comfort level from the observed ESER onset of that patient.

[0047] Figures 4-8 cover stim at 33Hz and 2Hz under otherwise identical conditions. Figures 4-5 show recordings obtained from several electrodes of the cochlear implant 10, at a given stimulus current. In particular Figure 4 illustrates respective recordings 402, 404, 406, 408 obtained from electrodes E1, E5, E8 and E14 following the application of a 1.9 mA stimulus, while Figure 5 illustrates recordings 502, 504, 506, 508 obtained from electrodes E1, E5, E8 and E14 following the application of a 1.8 mA stimulus.

[0048] In Figure 4 it can be seen that the 1.9 mA stimulus (not shown, concluding at 0 ms) gives rise to evoked compound action potentials (ECAPs) during a roughly 2 ms time period 412. Later, during a time period 414 centred at about 5 ms after the stimulus, another bioelectrical response emerges in the recordings 402, 404, 406 and 408, presenting a clearly observable peak. Any suitable detector may be utilised by the processor 12, controller 116, or other device, in order to detect the existence, peak magnitude, power, latency or other characteristic of such a signal component. Figure 4 is to be contrasted with Figure 5, in which a slightly smaller stimulus current of 1.8 mA continues to give rise to ECAPs during time period 512, but gives rise to a much reduced signal component during time period 514. This indicates that a stimulus current in the vicinity of 1.8 mA - 1.9 mA crosses a threshold for the bioelectrical response in time period 414/514.

[0049] It is noted that the recordings of Figures 4-8 illustrate the generation of signal components within time period 414/514, when the stimulus applied by a cochlear implant electrode rises past a threshold. Without intending to be limited by theory, this corresponds with the time of onset of the stapedius reflex as observed for example with a needle electrode. However, irrespective of the mechanism which gives rise to the observed signal components within time period 414/514, the present invention pertains specifically to making observations of those signal components within time period 414/514 and using them as a means to estimate a patient's comfort level or an analogue thereof such as the M level.

[0050] A further candidate for serving as a diagnostic is also revealed in the different behaviour of the recordings from different electrodes. In this experiment which produced Figures 4 and 5, electrode E1 was outside the round window, and hence a different electrical distance from the stapedius as compared to electrodes E5, E8, E14. In time period 416 arising around 2.6ms after stimulus, the recording is larger in amplitude on E1 than the other electrodes, whereas in time period 414 the recording from E1 is smaller than the other electrodes. The same

effect occurs in Figure 5. This inter-electrode variation thus presents a further signal characteristic by which the ESER may be discriminated from other signal components.

[0051] Figures 6-8 show how the recordings obtained from electrode E8 of the cochlear implant 10 change with stimulus current. In Figure 6, the recordings 602, 604, 606, 608, 610, 612, 614, 616 are obtained in response to electrical stimuli delivered at current levels of 0.9 mA, 1.3 mA, 1.6 mA, 1.6 mA, 1.8 mA, 1.9 mA, 2.0 mA, 2.2 mA, respectively, at 33 Hz. As can be seen, at stimuli levels up to about 1.6 mA, ECAPs are evoked in the time period 0-2ms, but no signal components are evident in the time period 4-7 ms. In contrast, as the stimulus current rises past 1.6 mA, recordings 608-616 exhibit increasing signal components in the time period 4-7 ms, consistent with gradual onset of a stapedius reflex.

[0052] Figure 7 provides a longer duration section of another set of recordings, obtained over a duration of 20 ms, to show later components of the recorded signals in response to the delivery of stimuli at 2 Hz. Again, the threshold for the onset of a response in the 4-7 ms time period can be seen to be between 1.5 mA and 1.8 mA. When stimming at 2 Hz, a 6ms component appears at 1.4mA. Figures 6 – 8 further illustrate that a latency of a peak of the signal component in the 4-7 ms range decreases with increasing current. Thus, the latency of such a signal component may also be used as a diagnostic for present purposes. At 1.8mA, though, another component appears and swamps it - this second component grows but its latency doesn't change. There is a component at 2.6ms which appears at the same or slightly lower current, which may be part of the reflex loop.

[0053] Figure 7 also exhibits subtler components in the time period 10-15ms following the stimulus, at stimulus levels >1.8mA, which aren't seen when stimulating at 33 Hz.

[0054] Without intending to be limited by theory,, all or any or none of these signal components observed in the time periods of 2-4 ms after the stimulus, 4-7 ms after the stimulus and/or 10-15 ms after the stimulus, could reflect the stapedius reflex or the activation of a different neural or muscular system and may hence present a useful proxy for the later perceptual effects on the patient. However, irrespective of the mechanism which gives rise to the observed signal components within such time periods, the existence, magnitude, power, and/or latency of signal components in the recordings from cochlear implant electrodes during such time periods may present a measurable effect which may be used to obtain an objective measure of a patient's comfort level or their cochlear implant fitting in general.

[0055] In another aspect of the present disclosure, it is noted that the stimulation threshold of nerve fibres varies depending on their prior exposure to stimulation fields. These accommodation effects can take the form of an increase or decrease in the stimulation threshold, and multiple accommodation effects can be present simultaneously. These may take periods from milliseconds to minutes to manifest during continuous stimulation, and may take from milliseconds to minutes to return to normal after stimulation is discontinued.

[0056] Accommodation occurs in neurostimulation applications generally and is not limited to cochlear neurostimulation. Thus, while the following examples are specific to cochlear stimulation the scope of the present invention in respect of providing solutions for accommodation is not limited to cochlear stimulation and applications of such solutions to other domains of neurostimulation are expressly within the scope of the present invention.

[0057] A block diagram of a conventional cochlear implant is shown in Figure 9. A microphone signal is amplified, then fed via a sensitivity control to an AGC. The AGC output then feeds an array of band-pass filters (BPF), each tuned to a different frequency. The energy of the output of each of these filters are detected and converted to a logarithmic scale (DET). For each channel, the signal amplitude is mapped to a charge value (MAP) which then controls a stimulator which delivers charge metered non-overlapping pulses to the cochlea.

[0058] A conventional mapping between sound intensity and stimulation intensity is shown in Figure 10. A sound below a certain amplitude SPL(T) produces no stimulation. If the stimulation intensity exceeds SPL(T) then it is mapped into a logarithmic current growth curve up to SPL(C) corresponding to stimulation at Q(C). For sound pressure above SPL(C) the stimulation does not increase. This mapping occurs for each channel, and thus for each electrode. The SPL(T) and SPLIC) are controlled by the gain of the amplifier, the sensitivity control and the AGC.

[0059] The Q(C) and Q(T) values are set using a process called "psychophysical mapping", or just "psychophysics". During psycho-physics each electrode is stimulated at a fixed rate, typically 1 KHz. The point at which a recipient can just detect the stimulation is called "T level". The signal level is increased until the patient finds that it is the maximum value that remains comfortable or "C level". This is repeated on each electrode. This process is equivalent to playing a single-tone sine wave into the speech processor at SPL(T) and then adjusting Q(T) until it can just be heard. Then presenting a tone at SPL(C) and increasing the charge till it is just comfortable.

[0060] There remains a range of problems with traditional psycho-physics. A first problem with traditional psycho-physics is that when complex sound across a broader spectrum is played into a speech processor, it sounds a lot louder than the loudness of a single tone or psycho-physics stimulation train of corresponding amplitude. To offset this, clinicians usually lower the Q(T) across all electrodes by a fixed amount $A < 1$, as shown in Figure 11, so the value used for $Q(T) = A.Q(PSY\ T)$. Usually the comfort level is preserved so $Q(C) = Q(PSY\ C)$.

[0061] A second problem with traditional psychophysics is that it is unsuitable for people without language, such as infants. To find the Q(T) and Q(C) for infants, one can measure the evoked response of the cochlea using electrical measurement of signals evoked on the nerve, sometimes called neural response telemetry (NRT). For each electrode, at a fixed stimulation rate, there is threshold charge where an evoked response can be measured Q(NRT T). However the measurable level is usually well above the true threshold, between Q(T) and Q(C), and a second arbitrary scale factor B must be used as shown in Figure 12.

[0062] The following examples of the invention thus provide means to simplify the prior mapping process in cochlear implants and to improve their design.

[0063] The present invention recognises that a first phenomenon that explains the contradictory results above is “adaption”, or accommodation. The sensitivity of a nerve cell stimulated just once is greater than a nerve cell stimulated multiple times; i.e. the sensitivity falls and the stimulation threshold rises if stimuli are repeated at too high a rate.

[0064] An example of adaptation is shown in Figure 13. When a sequence of identical stimulus pulses is delivered, as shown in the upper plot of Figure 13, the ECAP evoked by each stimulus is diminished over time as shown in the lower plot of Figure 13. This is a case of inhibitory accommodation, where the stimulation threshold is increased; excitatory accommodation may also occur and causes the stimulation threshold to decrease.

[0065] Cochlear implant speech processing algorithms continuously select different sequences of stimuli to deliver in order to approximate the incoming sound signal. This uses a stimulation map for each electrode, which is determined statically from T and C when the patient is fitted. The map determines the correct stimulus intensity to deliver in order to evoke the sensation of a given sound intensity (loudness).

[0066] During stimulation with speech, the nerve fibres near each electrode will be subjected to varying patterns of stimuli. In the presence of accommodation effects, their thresholds will be constantly changing. A static stimulation map assumes that these thresholds are unchanging, and so will not provide the desired neural recruitment.

[0067] In this embodiment, a dynamic map is used to compensate for accommodation effects. This map takes into account the stimuli which have been previously delivered to each electrode, and can then be used to determine the appropriate stimulus intensity to achieve a desired loudness value.

[0068] Figure 14 shows a schematic of data flow in a cochlear implant. Audio input is processed by a speech processor, which schedules stimuli on different electrodes and with different loudnesses to reproduce the input sound. The stimulation map maps the desired loudness of a stimulus to an electrical stimulus intensity for that stimulation electrode. A pulse generator then delivers the stimuli to the desired electrode. The present invention recognises that a dynamic mapping can be implemented by adjusting the stimulation map in real time depending on the neural accommodation arising from recently applied stimuli.

[0069] A dynamic map requires a model of the accommodation effects expected to arise from given recently applied stimuli. This model may be fitted to the patient during initial implant fitting, by delivering a sequence of probe stimuli and recording the ensuing evoked compound action potentials (ECAPs) using an amplifier and ADC. The evoked action potentials indicate the level of achieved neural recruitment from each stimulus, allowing accommodation effects to be measured.

[0070] An example of a probe sequence is a periodic train of identical pulses. Accommodation will manifest as a change in the ECAP amplitude as a function of time from start of the sequence. This is similar to measuring the step response in a control system. Probes may also be adjusted to achieve a constant recruitment and/or constant ECAP amplitude. Random and pseudorandom sequences are also useful for system identification. The common engineering techniques of model identification and channel estimation are applicable to this problem.

[0071] A first embodiment of the present invention for implementation of a dynamic map is shown in Figure 15. In this map, a model estimates the deviation in threshold as a result of prior

stimuli. This threshold estimate is used to scale the stimulus intensity determined with a traditional static map.

[0072] A simple form of such a model is:

$T(t) = pG(\max(I(t) - R, 0)) + T_0$

where:

a. $I(t)$ is the delivered stimulus waveform,

b. R is a stimulus intensity at which accommodation begins to occur,

c. $G()$ is a single-pole low-pass filter, whose gain models the degree of accommodation and whose time constant models that of the accommodation process,

d. p is +1 for an excitatory and -1 for an inhibitory accommodation process,

e. T_0 is the unaccommodated threshold.

[0073] The parameters for G and p can be determined by measuring the step response: starting from a state at rest, delivering a regular train of stimuli of constant amplitude, and measuring the amplitude of the resulting ECAPs. The change over time allows the degree and time constant to be fitted. T_0 can be measured using widely spaced stimuli delivered from a resting state to find the unaccommodated threshold directly. Measuring psycho-physical threshold based on a single stimuli is thus an important element of such embodiments of the present invention.

[0074] The dynamic map of Figure 15 estimates the threshold of the target nerves and scales the total stimulation; i.e. it effectively adjusts both the T and C levels of the map. In other embodiments a more advanced dynamic map may adjust the T level according to the model's threshold estimate whilst leaving the C level constant. A dynamic map may also switch between mapping curves depending on the state of the model.

[0075] Simple models may treat each electrode independently, assuming that stimulation on one electrode does not affect the thresholds at nearby electrodes. Figures 16 and 17 show such systems, in which a separate, independent dynamic map is used for each of N electrodes. Adjustment of T and C levels is based on NRT measurement of adaption. By measuring the NRT thresholds on individual electrodes during live speech, it is possible to measure the level of their adaption. This can then be used to adjust the T and C levels.

[0076] In more advanced embodiments, MIMO model techniques are used to model interactions between nearby electrodes. Figures 18 and 19 show embodiments where the dynamic model is split. A common model is used which takes into account the N different stimulus waveforms' history, and the N model outputs are fed to the per-channel dynamic mapping system. Figure 19 shows that the overall level of stimulation, being the primary contributor to loudness summation, can also be calculated by combining the outputs of the individual detectors, and then automatically adjusting the mapping processes. The loudness summation in Figure 19 may in another embodiment (not shown) be output to the AGC for AGC control.

[0077] In yet another embodiment, shown in Figure 20, an adaptive filter is used to determine the correct stimulus intensity in the presence of neural accommodation. The desired stimulation is mapped to, or expressed in, some characteristic of the ensuing ECAP, such as the amplitude of an ECAP component, the latency of an ECAP component, or the output of a detector applied to the ECAP waveform. The filter then estimates the correct stimulus intensity to produce the desired ECAP characteristic. When the stimulus is applied, the ensuing ECAP characteristic is measured. The difference between the desired and actual characteristic value forms an error term which is used to adapt the filter.

[0078] It will be appreciated by those skilled in the art that any of the existing body of work in adaptive filters may be adapted to this task, such as least mean squares filtering, recursive least squares filtering, et cetera. It is desirable that the filter have an affine characteristic which represents the threshold current required to begin producing neural recruitment and hence an ECAP.

[0079] When no stimulus is desired on the selected channel, the pulse generator is not activated, regardless of the filter output. The filter's internal state is still updated; this may be performed on every timestep, or the update for several timesteps may be applied immediately before the next filter prediction is required. The filter's adaptation may be inhibited, and no ECAP recorded, during periods when no stimulus is delivered on that channel. In a MIMO filter application, parts of the filter model may be selectively updated depending on the stimulation pattern.

[0080] An example of such a system, applied to a cochlear implant, is shown in Figure 20. The traditional map from loudness to stimulus intensity is replaced with one from loudness to

desired ECAP amplitude. To a first order approximation, ECAP growth is roughly linear with stimulus intensity above T, so a traditional map can be used with T=0 and C determined by the patient's ECAP at comfort level.

[0081] In this implementation, the ECAP amplitude is the controlled characteristic. The ECAP detector may take a peak-to-peak voltage measurement, take the dot product of the ECAP recording with a desired filter kernel, or measure any other desired characteristic of the ECAP.

[0082] An adaptive filter may also be used in a MIMO configuration, in which the filter has N inputs and N outputs. The desired ECAP levels on each of N channels are fed in simultaneously; typically, this will be zero on all bar one channel. Similarly, only one channel's output will usually be delivered using the pulse generator on each time step. In a MIMO configuration, the filter adaptation may be suppressed on channels which are not delivering stimulation and recording ECAPs.

[0083] A dynamic map or adaptive filter may be configured or trained during patient fitting, using training-specific stimulation sequences, with the determined settings being retained during subsequent therapeutic stimulation. Maps and filters may also be configured or trained during regular speech processing stimulation. ECAPs can be recorded from therapeutic/sensory stimuli, rather than specific probe stimuli. These adjustments may be performed on every stimulus, or only intermittently on some stimuli or during some periods of stimulation.

[0084] It will be appreciated by persons skilled in the art that the approaches described here are applicable not only to the cochlear nerve but can also be applied to any neuromodulation target where accommodation occurs and accurate, information-bearing stimuli must be delivered. This includes auditory brainstem implants, retinal prostheses, and other sensory prostheses.

[0085] This method may also use multi-dimensional maps to control multiple parameters simultaneously. These maps may have multiple inputs: for example, a visual prosthesis may control both brightness and spot size of a stimulus. These maps may have multiple outputs: for example, the pulse width and current of a stimulus may be independently controlled.

[0086] It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present

embodiments are, therefore, to be considered in all respects as illustrative and not limiting or restrictive.

CLAIMS:

1. A method of determining a cochlear implant recipient's comfort level, the method comprising:

delivering electrical stimuli from at least one electrode of an implanted cochlear implant to the cochlear nerve;

using at least one electrode of the implanted cochlear implant to obtain recordings of neural responses evoked on the cochlear nerve by the electrical stimuli; and

inspecting the recordings to detect a diagnostic signal component and determining the comfort level from an observed onset of the diagnostic signal component.

2. The method of claim 1 wherein inspecting the recordings to detect a diagnostic signal component comprises inspecting a time period of substantially 1-20 ms after the stimulus.

3. The method of claim 2 wherein inspecting the recordings to detect a diagnostic signal component comprises inspecting a time period of substantially 1-7 ms after the stimulus.

4. The method of claim 3 wherein inspecting the recordings to detect a diagnostic signal component comprises inspecting a time period of substantially 4-7 ms after the stimulus.

5. The method of claim 3 or claim 4 wherein inspecting the recordings to detect a diagnostic signal component further comprises inspecting a time period of substantially 1-3 ms after the stimulus.

6. The method of claim 2 wherein inspecting the recordings to detect a diagnostic signal component comprises inspecting a time period of substantially 10-15 ms after the stimulus.

7. The method of any one of claims 1 to 6 wherein a recording obtained from a basal electrode is compared to a recording obtained from a more apical electrode in order to discriminate a diagnostic signal component.

8. The method of claim 7 wherein a recording obtained from an extra-cochlear electrode is compared to a recording obtained from an intra-cochlear electrode in order to discriminate a diagnostic signal component.

9. The method of claim 7 or claim 8 wherein the comparison is of a time period of substantially 2-4 ms after the stimulus in each such recording.

10. The method of any one of claims 7-9 wherein the comparison is of a time period of substantially 4-7 ms after the stimulus in each such recording.

11. The method of claims 9 and 10 wherein a relatively stronger signal component in the basal electrode recording in the time period of substantially 2-4 ms after the stimulus coinciding with a relatively stronger signal component in the apical electrode recording in the time period of substantially 4-7 ms after the stimulus is taken to be a diagnostic signal component.

12. The method of any one of claims 1 to 11 wherein a latency of a signal component is determined in order to discriminate a diagnostic signal component.

13. The method of claim 12 wherein a reduction in latency with an increase in stimulus current is taken to be a diagnostic signal component.

14. The method of any one of claims 1 to 13 wherein determining the comfort level from an observed onset of the diagnostic signal component comprises applying an empirically derived calculation to the stimulus current at which onset of the diagnostic signal component occurs.

15. A device configured to determine a cochlear implant recipient's comfort level, the device comprising:

a stimulation controller configured to control the delivery of electrical stimuli from at least one electrode of an implanted cochlear implant to the cochlear nerve;

a recording controller configured to control the recording by at least one electrode of the implanted cochlear implant of recordings of neural responses evoked on the cochlear nerve by the electrical stimuli; and

a processor configured to inspect the recordings to detect a diagnostic signal component and to determine the comfort level from an observed onset of the diagnostic signal component.

16. A method of dynamically adjusting neural stimuli to compensate for neural accommodation, the method comprising:

adjusting a stimulus by reference to a stimulation history and a map of neural accommodation in order to define an adjusted stimulus; and

delivering the adjusted stimulus to neural tissue.

17. The method of claim 16 wherein the map of neural accommodation is dynamic.

18. The method of claim 16 wherein the map of neural accommodation is static, and wherein the adjusting further utilises an accommodation model.

19. The method of claim 18 wherein the accommodation model is fitted and/or adjusted using measurements of ECAPs.

20. The method of claim 19 wherein ECAPs are measured after selected or all stimuli during normal use of the neurostimulator.

21. The method of any one of claims 18-20 wherein the accommodation model is fitted and/or adjusted using measurements of ECAPs at a time of fitting or installation of a neurostimulator, by use of probe stimuli to evoke the ECAPs.

22. The method of claim 21 wherein the probe stimuli comprise a constant amplitude train of stimuli.

23. The method of claim 21 wherein the probe stimuli are of variable amplitude configured to produce constant amplitude ECAPs.

24. The method of claim 21 wherein the probe stimuli comprise a pseudorandom sequence.

25. The method of any one of claims 21 to 24 wherein the probe stimuli are delivered on multiple electrodes for MIMO accommodation mapping.

26. The method of any one of claims 18-25 wherein the accommodation model adjusts a static stimulation map.

27. The method of claim 26 wherein the adjustment comprises scaling T while leaving C unchanged.

28. The method of claim 26 wherein the adjustment comprises scaling total stimulus intensity so that both T and C are adjusted.

29. The method of claim 26 wherein the adjustment comprises selecting different map curves depending on state or stimulation history.

30. The method of any one of claims 18-29 wherein the accommodation model applies to a single electrode, and takes into account only the stimulation history of that electrode

31. The method of any one of claims 18-29 wherein the accommodation model applies to a plurality of electrodes and reflects a stimulation history of the plurality of electrodes.

32. The method of any one of claims 18-31 wherein the accommodation model comprises a linear filter.

33. The method of claim 32 wherein an input of the linear filter is clamped.

34. The method of claim 32 wherein a state variable of the linear filter is clamped.

35. The method of any one of claims 16 to 34 further comprising adaptive filtering to evoke consistent neural response in the presence of accommodation.

36. The method of claim 35 wherein the adaptive filter is trained using the difference between desired and recorded characteristic.

37. The method of claim 36 wherein filter training is suppressed during periods without stimulation.

38. A device for dynamically adjusting neural stimuli to compensate for neural accommodation, the device comprising:

a recording medium holding data defining a map of neural accommodation;

a signal processor for taking an input signal and determining a stimulus therefrom, and for adjusting the stimulus by reference to a stimulation history and the map of neural accommodation in order to define an adjusted stimulus; and

a stimulus generator for generating the adjusted stimulus for delivery to neural tissue.

39. A method of training a system for compensating for neural accommodation, the method comprising measuring neural accommodation characteristics arising in response to a sequence of stimuli, and defining a map of neural accommodation.

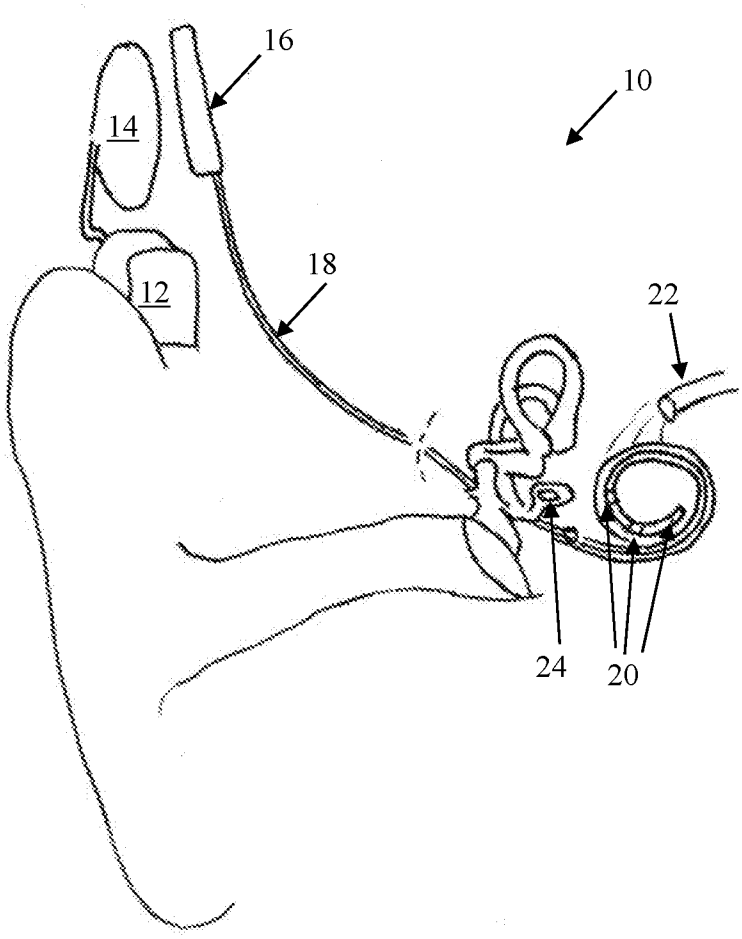

Figure 1

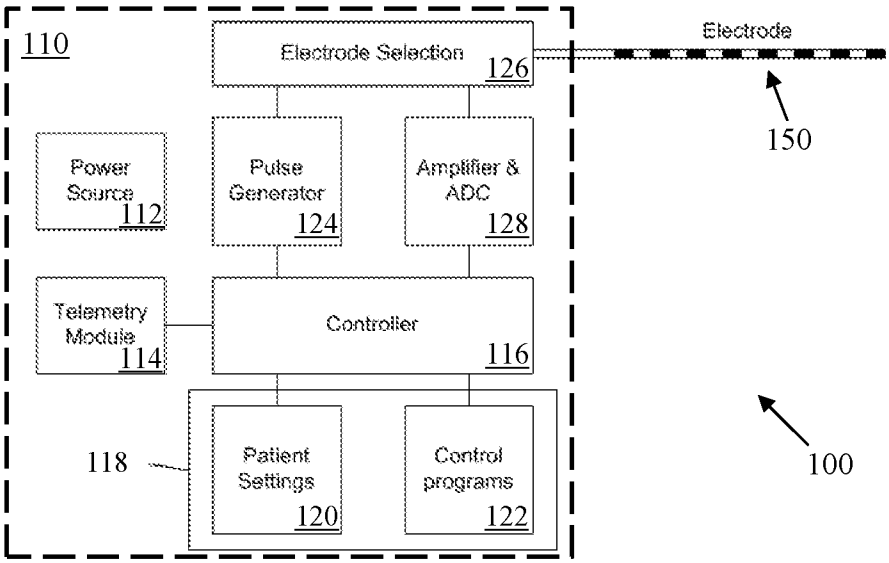

Figure 2

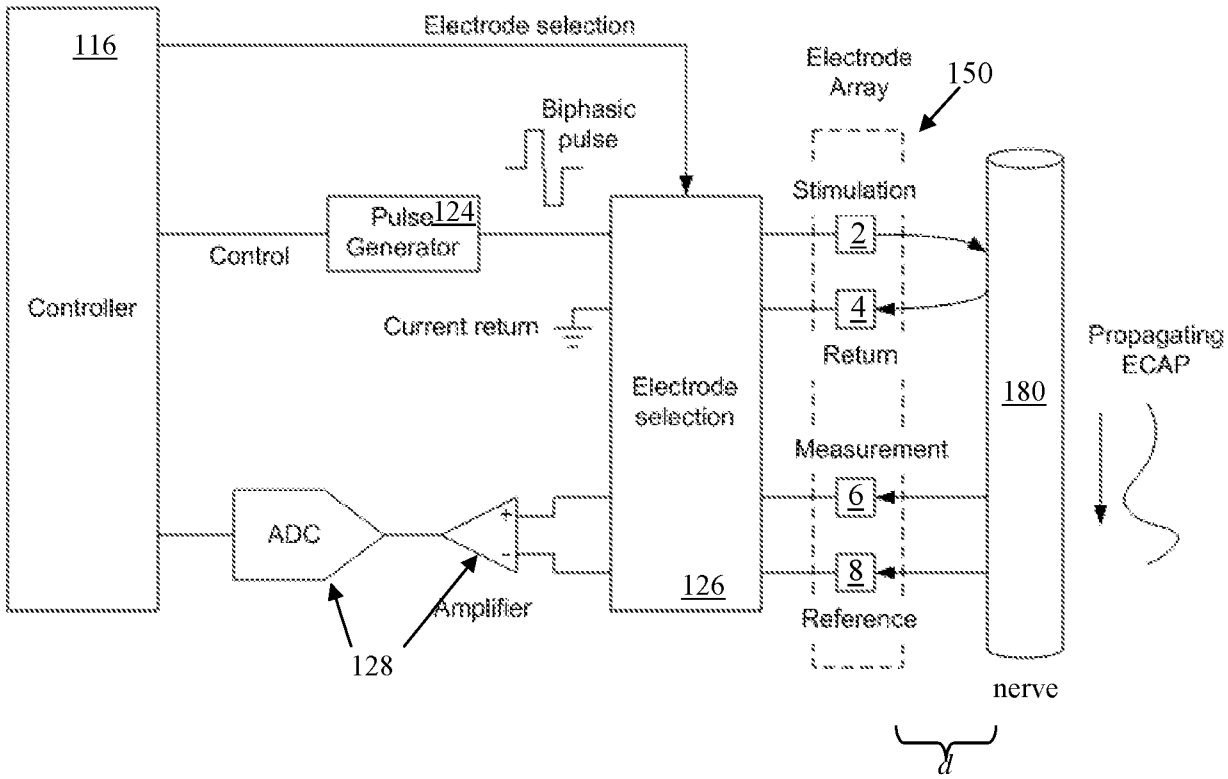

Figure 3

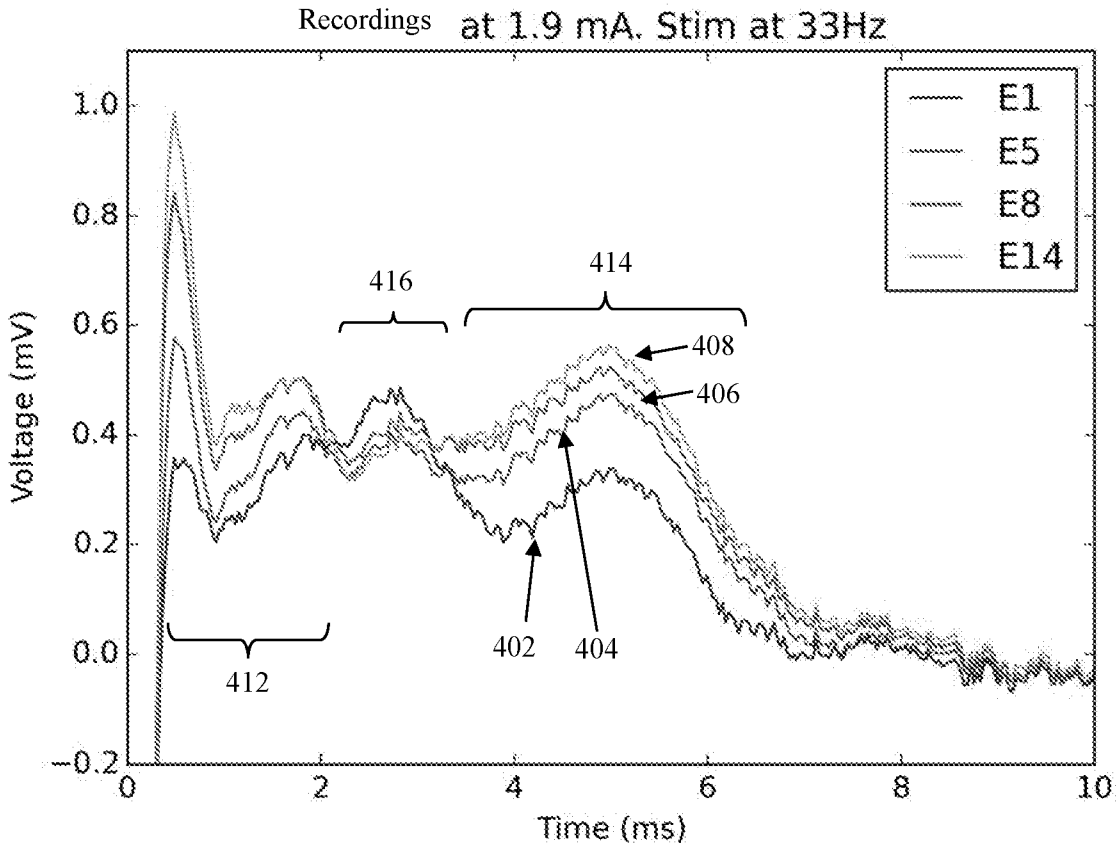

Figure 4

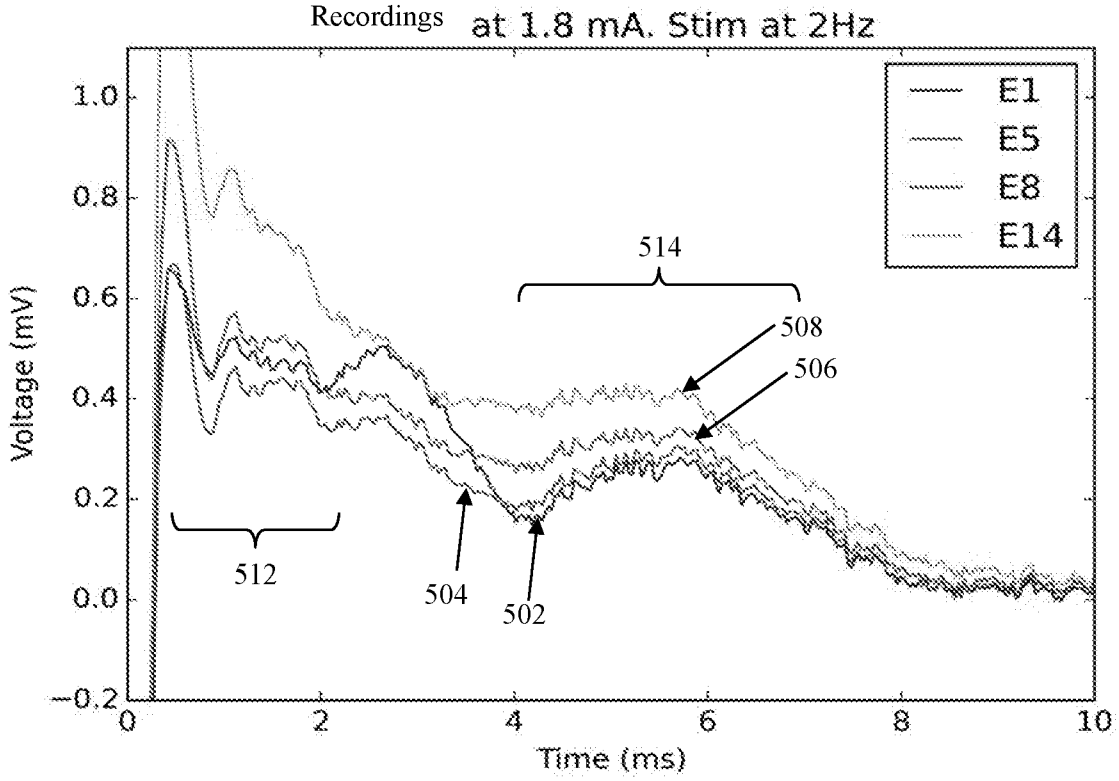

Figure 5

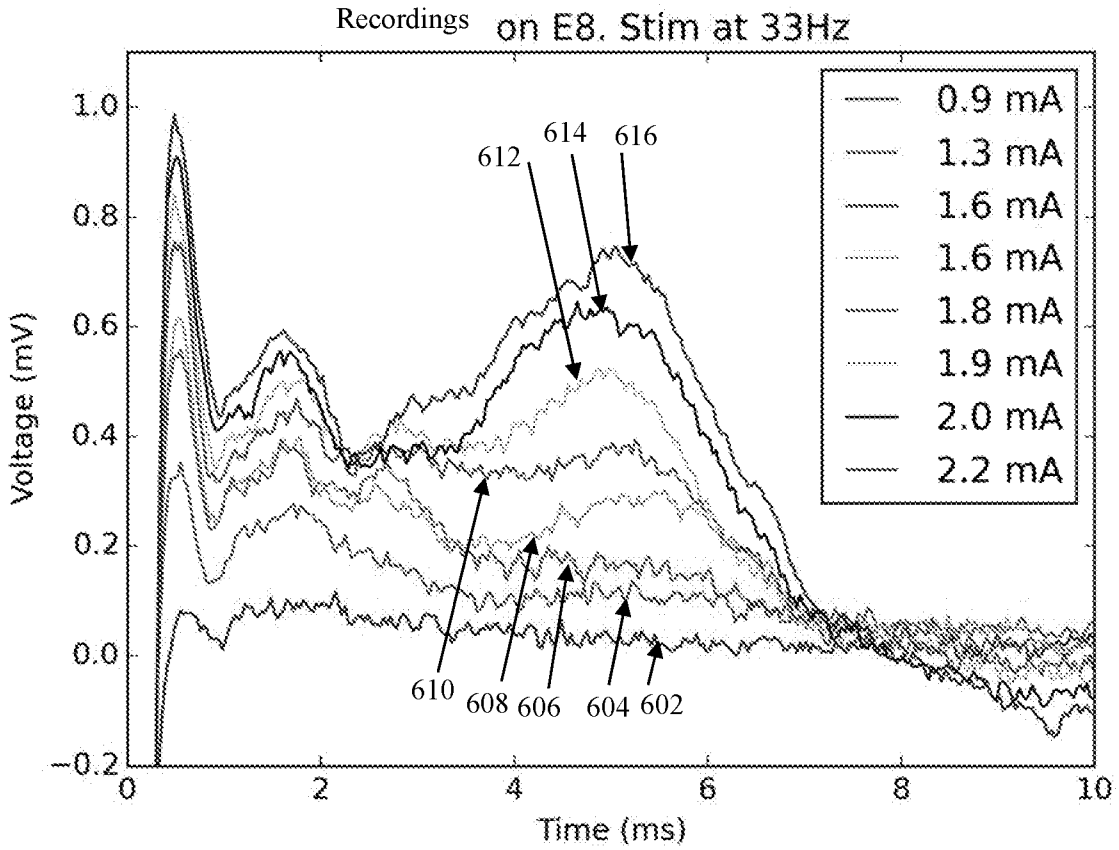

Figure 6

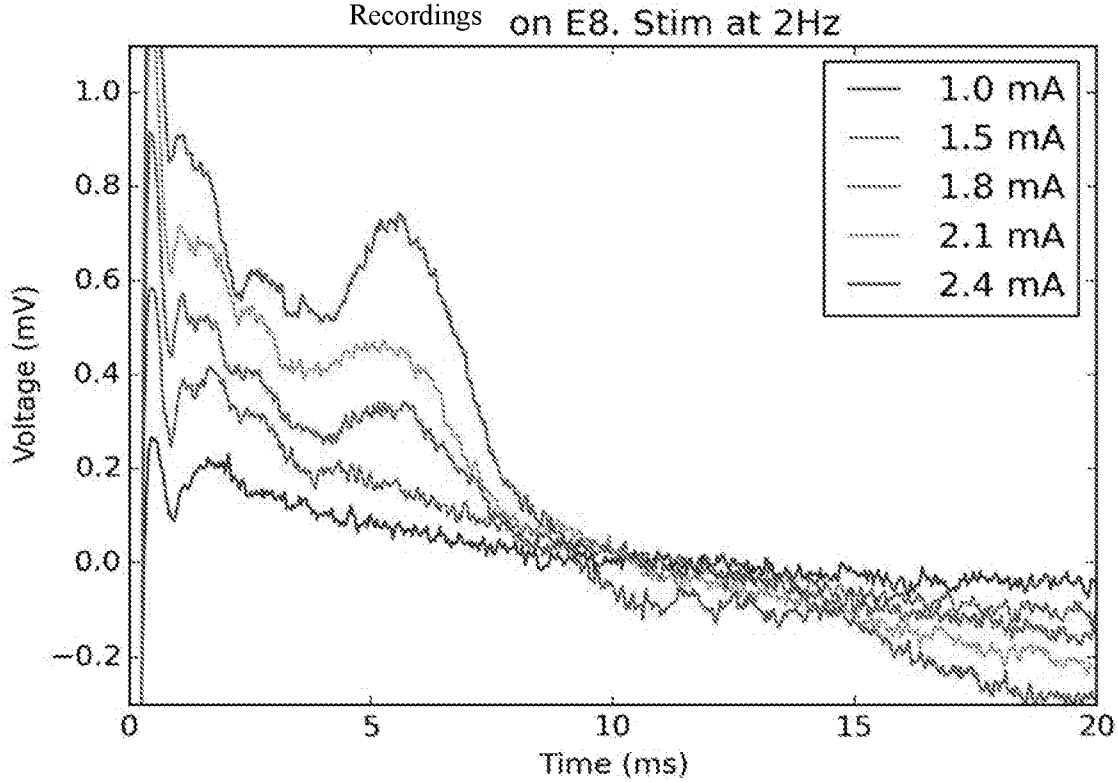

Figure 7

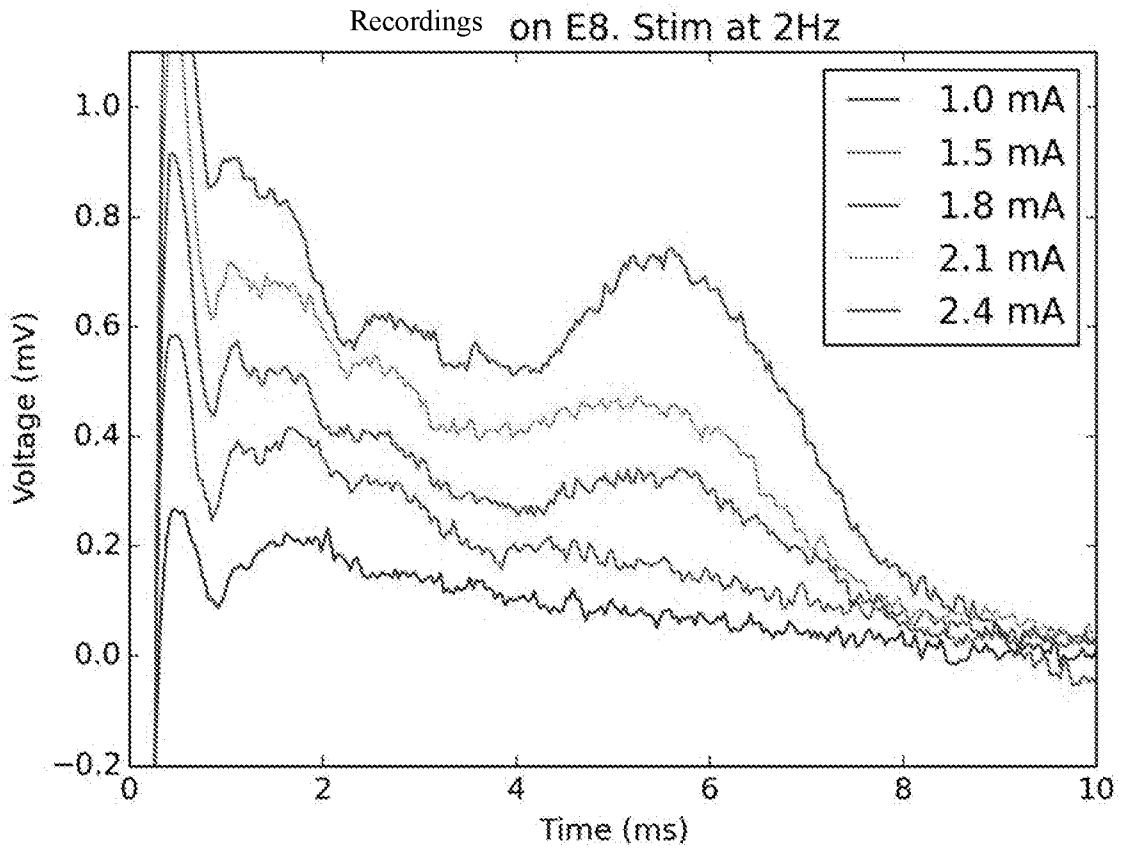

Figure 8

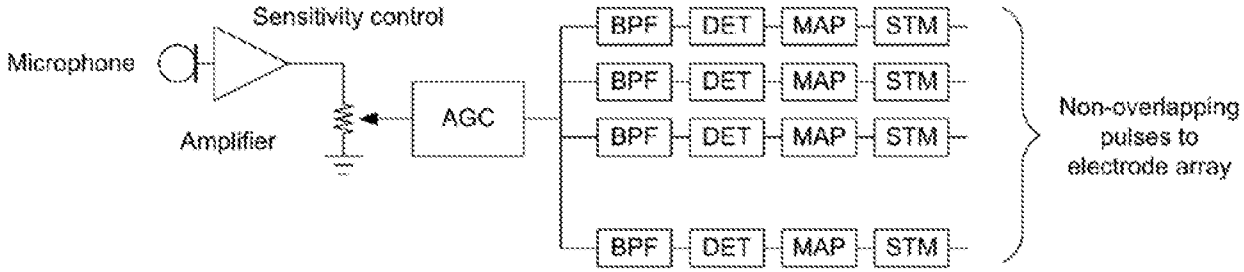

Figure 9 – Prior Art

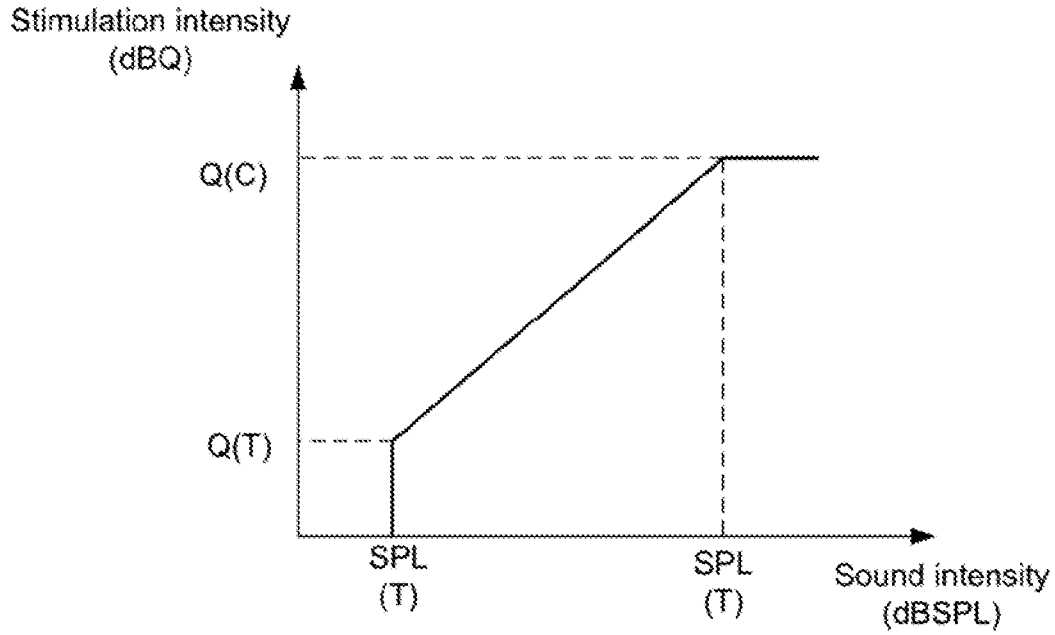

Figure 10 – Prior Art

(C)

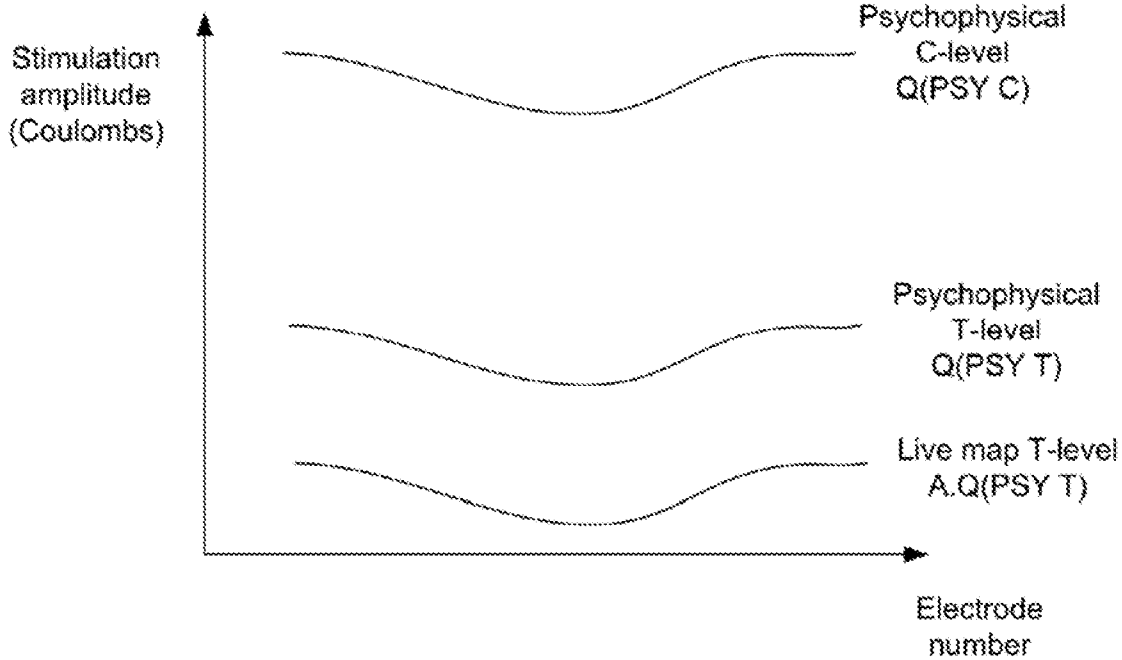

Figure 11 – Prior Art

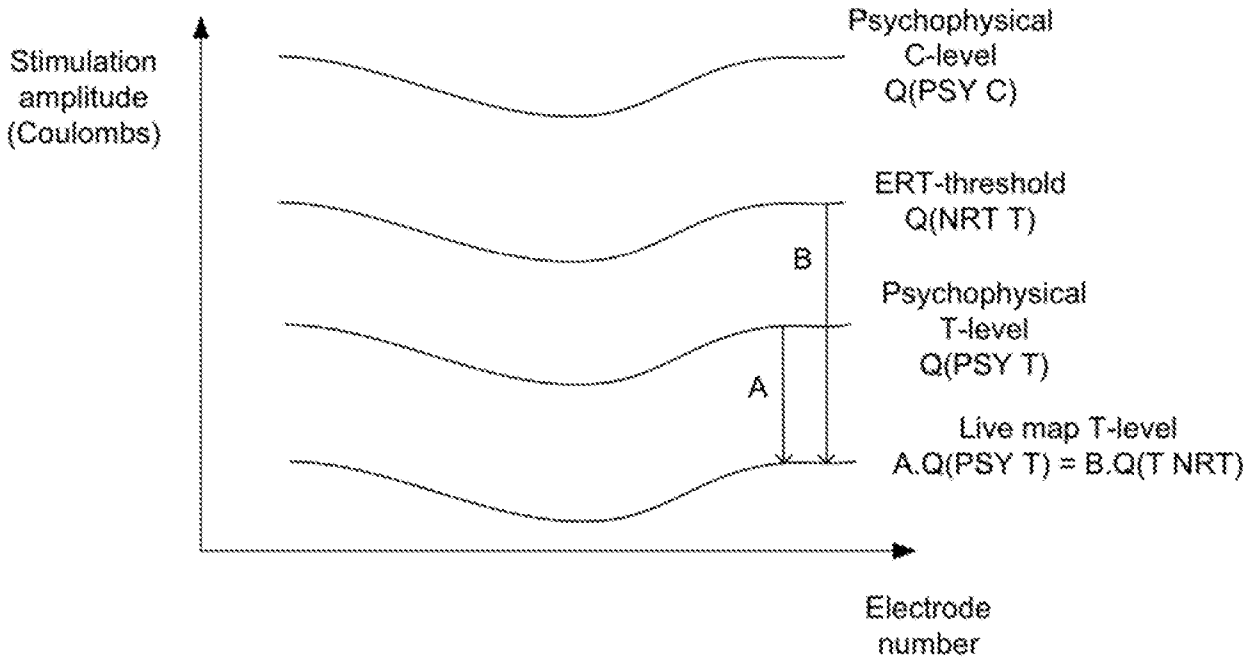

Figure 12 – Prior Art

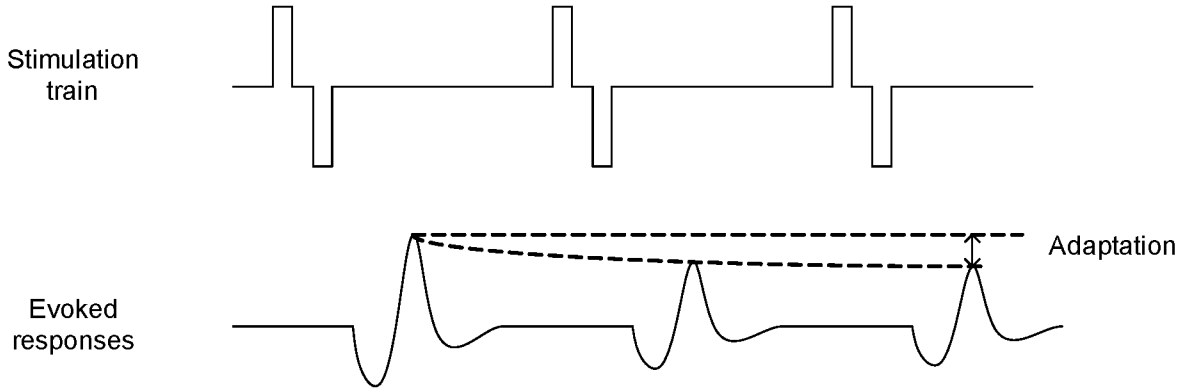

Figure 13

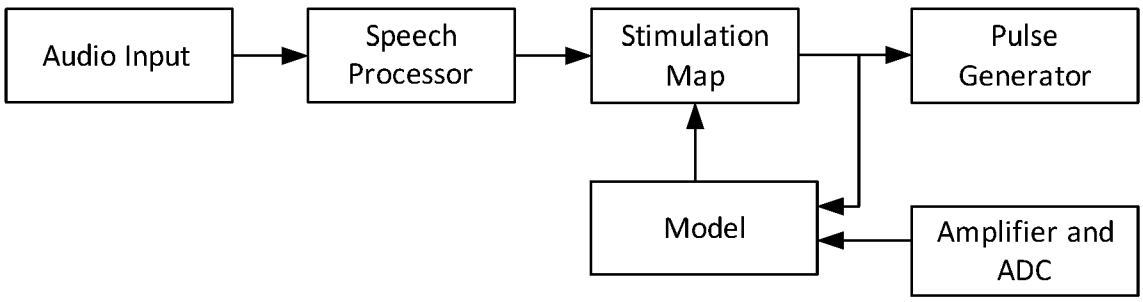

Figure 14

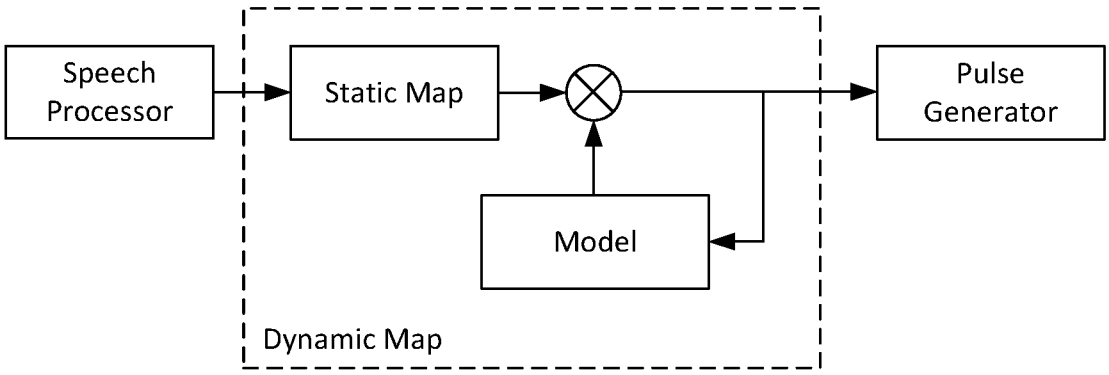

Figure 15

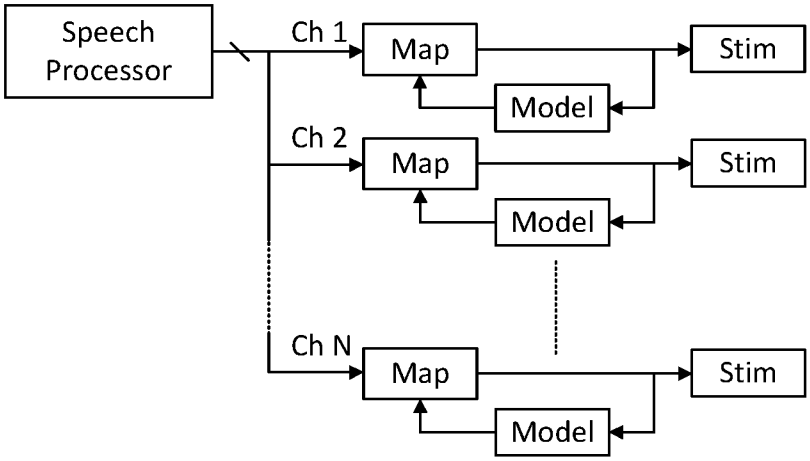

Figure 16

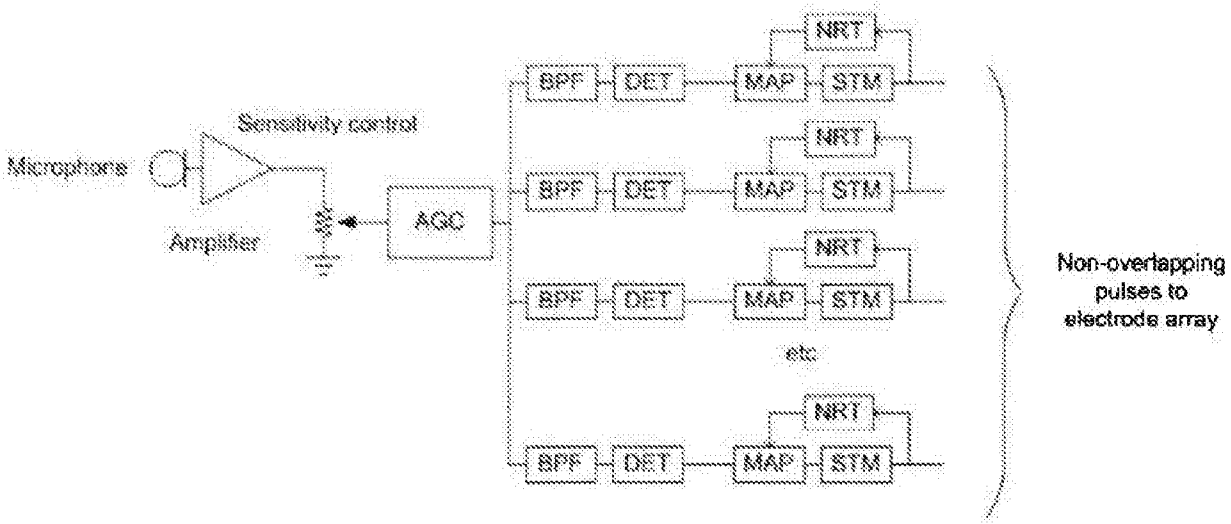

Figure 17

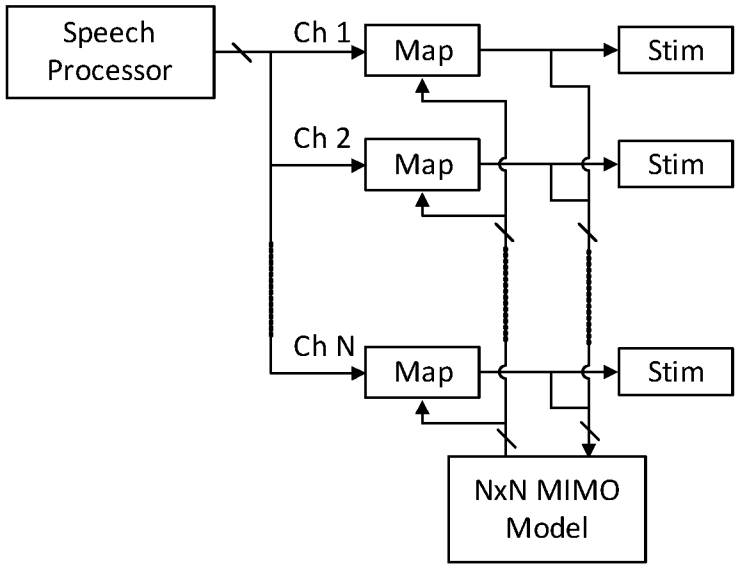

Figure 18

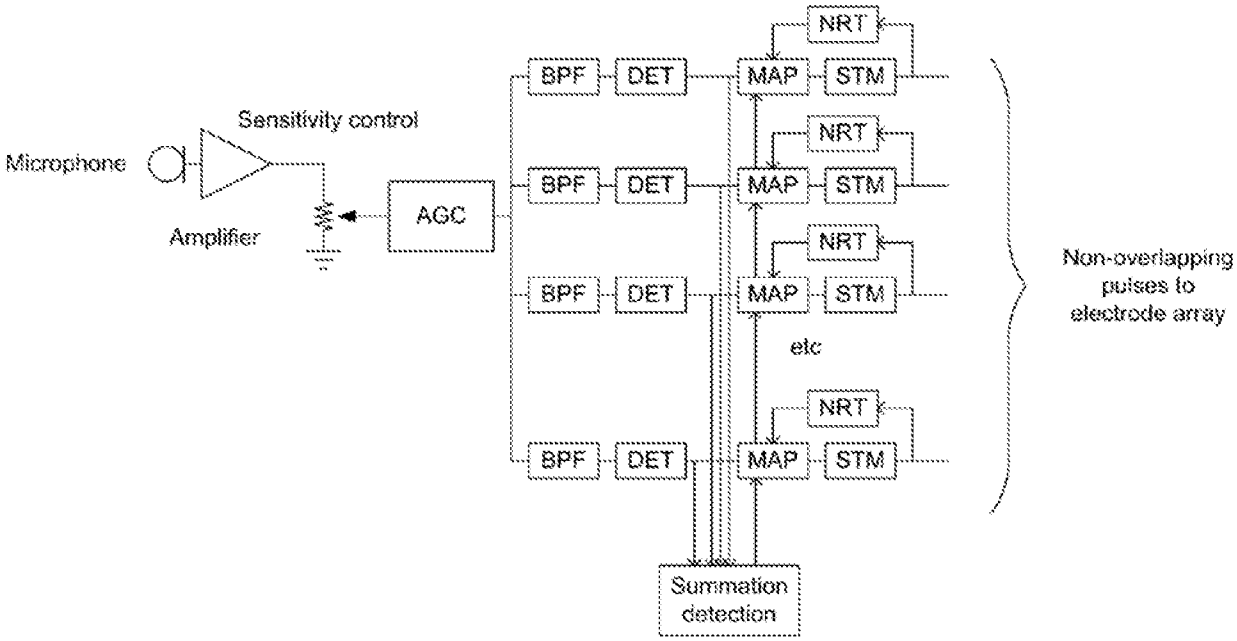

Figure 19

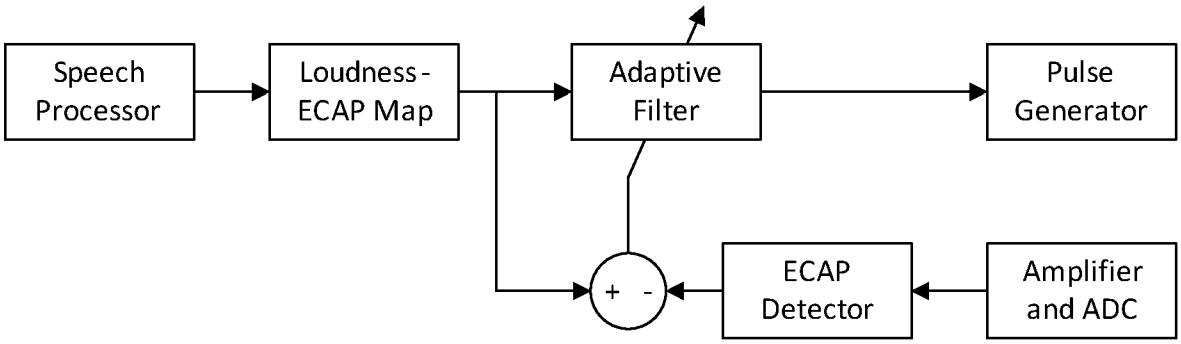

Figure 20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2016/051259

A. CLASSIFICATION OF SUBJECT MATTER

A61N 1/36 (2006.01) A61N 1/05 (2006.01) A61N 1/372 (2006.01) A61B 5/04 (2006.01) H04R 25/00 (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC, WPIAP and IPCs: A61N1/36, A61N1/05, A61N1/372, A61B5/04, H04R25/00 and CPCs: A61N1/36032, A61N1/37241, A61N1/37252, A61N1/0541, with further limiting by keywords: evoked potential, Evoked response, adapt, ECAP, cochlear implant, dynamic, adaptive and the like.

Google Patents and Google Scholar with keywords: ECAPs, evoked potential onset, signal characteristics, determination, cochlear, nerve adaptation and the like.

Applicant(s)/Inventor(s) name searched in internal databases provided by IP Australia.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 April 2017	24 April 2017
Name and mailing address of the ISA/AU	**Authorised officer**
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA Email address: pct@ipaustralia.gov.au	Viara Van Raad AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. +61 2 62832676

INTERNATIONAL SEARCH REPORT C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		International application No. **PCT/AU2016/051259**
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	HUGHES, M. "Fundamentals of Clinical ECAP Measures in Cochlear Implants Part 2: Measurement Techniques and Tips." Audiology Online, 2006, pages 1-7. (online journal) [retrieved from internet on 18 April 2017] URL:http://www.audiologyonline.com/articles/fundamentals-clinical-ecap-measures-in-965-965> Introduction, 2nd paragraph "...ECAP Measurements and their relations to programming levels ...upper comfort levels...", Fig. 4, part "Amplitude Measurement: Picking Peaks, Fig. 6 part "Finding Threshold" Fig. 8	1-15
X Y	US 2015/0018699 A1 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA et al.) 15 January 2015 Abstract, Figs. 2 to 5, Fig 6, part (A), Fig. 7 and 8; para[0011]-[0013], para[0027], para[0031]-[0043], esp. para[0043]; para[0045]-[0056], para[0075], para[0080]-[0084] Entire document	1-15 19-23
X	US 2012/0303095 A1 (KALS) 29 November 2012 Abstract, para[0006]-[0020], para[0019], [0020], [0032]-[0042], Figs. 1-4, elements (108), (201), (305), (403)	1, 15, 16, 38, 39
X	US 2005/0261748 A1 (VAN DIJK) 24 November 2005 Abstract, para[0013], [0016], [0022], Figs. 1, 2a, 3b; para[0058], [0060], [0077], [0078], [0080], para[0076], [0086]-[0089], claims 12, 24 and 34, elements (100), (22), (33), (35), (41), (53), (55) Figs. 1 and 5	1, 15, 16, 38, 39
X Y	WO 2012/155188 A1 (NATIONAL ICT AUSTRALIA LTD.) 22 November 2012 Abstract; page 3, ln. 25-page 5, ln. 32; page 19, ln. 16-32; Figs. 21b, 25a,25b; Figs. 1, 7, 12, 13, 15, 16 and 18-24 Entire document	16-18, 24-39 19-23
A	US 6157861 A (FALTYS et al.) 05 December 2000 Entire document	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2016/051259

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
the subject matter listed in Rule 39 on which, under Article 17(2)(a)(i), an international search is not required to be carried out, including

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See Supplemental Box for Details

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Supplemental Box

Continuation of: **Box III**

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups:

- Claims 1-15 are directed to a method and a device for measuring a cochlear recipient's comfort level after a delivery of electrical excitation signal from at least one electrode and obtaining recording from at least another, sensing and/or recording electrode from a neural evoked response risen by the cochlear nerve after the application of the electrical stimulus and measuring the Evoked Compound Action Potential (ECAP). The feature of the measuring the recipient's comfort level is specific to this group of claims.

- Claims 16-39 are directed to a method and a device for dynamically adjusting of neural stimuli to compensate for neural accommodation by generating excitation stimuli according to adjusted stimulus for the delivery to the neural tissue and to provide a training system, and to define a map for neural accommodation. The feature of the said adjusting of neural stimulation (that includes exciting nerves and obtaining evoked response with records of such evoked response implicitly) to compensate for neural accommodation is specific to this group of claims.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

When there is no special technical feature common to all the claimed inventions there is no unity of invention.

In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claimed inventions and therefore cannot provide the required technical relationship. The only feature common to all of the claimed inventions and which provides a technical relationship among them is the excitation stimuli to the nerve (and inherently recording the evoked nerve response) to assess/measure the evoked action potential.

However it is considered that this feature is generic in this particular art. Therefore in this light this common feature cannot be a special technical feature. Hence there is no special technical feature common to all the claimed inventions and the requirements for unity of invention are consequently not satisfied a *priori*.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2016/051259**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		**Patent Family Member/s**	
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Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

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This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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End of Annex

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.